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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,656	12/21/2001	Aliassghar N. Tofighi	112430.121US1	5535
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HALE AND DORR, LLP 60 STATE STREET BOSTON, MA 02109			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3732	PAPER NUMBER
			DATE MAILED: 01/05/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,656

Applicant(s)

TOFIGHI ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 and 16-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 6,117,456).

Regarding claims 1-8, 10, 12, 13, 16-19, 21, 23 and 24, Lee et al. disclose a material for in vivo applications that can be formed or "machined" into an implant including an amorphous calcium phosphate ("first calcium phosphate"), a promoter or "second calcium phosphate" such as calcium metaphosphate, dicalcium phosphate dihydrate etc. as a precursor wherein the calcium to phosphate ratio is in a range of 1.1-1.9 (col. 1, lines 24-26, col. 4, lines 15-18 and lines 40-46, col. 7, lines 50-58, col. 8, lines 1-4 and lines 17-20, col. 12, lines 62-67, col. 13, lines 1-2 and lines 7-13 and col. 14, lines 57-66). It is the Examiner's position that the atomic ratio of calcium to phosphorus of the first calcium phosphate or the second calcium phosphate is an inherent property of the type of calcium phosphate selected as the first calcium phosphate or the second calcium phosphate, respectively. Lee et al. also disclose that the first calcium phosphate is amorphous and the second calcium phosphate may be amorphous or crystalline (i.e., different or greater crystallinity) (col. 11, lines 4-8 and col. 13, lines 17-19).

Although Lee et al. disclose a calcium to phosphate ratio between 1.2 and 1.68, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an atomic ratio of calcium to phosphorus between 1.2 and 1.68, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Further, Lee et al. disclose that a supplementary material may be added to the precursors to improve the hardness or compressive strength of the poorly crystalline hydroxyapatite (col. 22, lines 31-38 and col. 30, lines 54-57). Although Lee et al. do not disclose specific

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compressive strengths of 60 MPa or 120 MPa, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have adjusted the hardness or compressive strength of the poorly crystalline hydroxyapatite, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 9, 11, 20 and 22, Lee et al. disclose the addition of supplementary material such as biocompatible polymers in particulate (powder) or fiber form in the preparation of resorbable implants (col. 22, lines 63-67 and col. 23, lines 1-15 and lines 22-28).

Regarding claims 25, 28, 31 and 32, the method steps of (a) providing a bone implant as claimed, and (b) securing the bone at a site requiring implantation, whereby the precursor undergoes conversion to poorly-crystalline hydroxyapatite at the implantation site would be performed during normal use of the Lee et al. bone implant for bone implantation (see discussion for claims 1-8 and col. 9, lines 37-48).

Although, Lee et al. do not specifically disclose using the implant material for spinal fusion, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the poorly crystalline hydroxyapatite for spinal fusion, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 7.

Regarding claims 27 and 30, the method steps would be normally performed when the implant is placed in a human body due to curing of the Lee et al. precursor at a significantly accelerated rate at 37 °C (col. 5, lines 20-28 and col. 8, lines 39-55).

Regarding claims 26 and 29, the method steps would be normally performed depending on the kinetics or duration of the conversion of the precursors to poorly crystalline hydroxyapatite (col. 6, lines 6-30). Although Lee et al. do not disclose a duration between 2 weeks and about 6 weeks, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the precursor materials so that the duration of the conversion process is between 2 weeks and 6 weeks, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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Regarding claims 33-36, Lee et al. disclose the addition of bone regenerative proteins into poorly crystalline apatite to increase the rate of bone growth and accelerate bone healing (col. 23, lines 55-57).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Pending claims 1-13, 16-25, 27-28 and 30-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 15 and 22 of U.S. Patent No. 6,287,341 ('341) in view of Brown et al. (US 6,201,039).

Claim 16 of '341 discloses all limitations of pending claims 1-6, 13, 16, 24-25, 28, 31-32 except for compressive strength.

Claims 14 and 16 of '341 disclose all limitations of pending claims 7-8 and 18-19 except for compressive strength.

Claims 16 and 24 of '341 discloses all the limitations of pending claims 9-12 and 20-24 except for compressive strength.

Claims 16 and 22 of '341 discloses all the limitations of pending claims 33-36 except for compressive strength.

Brown et al. teach adjusting the liquid to precursor ratio to obtain a hydroxyapatite with a compressive strength of up to 175 MPa (col. 8, lines 38-48, col. 9, lines 7-15 and col. 12, lines 20-27).

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Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have adjusted the liquid to precursor ratio in claim 1 of '341, as taught by Brown et al., to adjust the compressive strength to 60 MPa or 120 MPa, depending on the type of bone in which the implant is to be placed.

The method steps of pending claims 25, 28, 31 and 32 are rendered obvious by the above discussion.

Pending claims 27 and 30 are rendered obvious by claim 20 of '341.

Regarding pending claims 31 and 32, Brown et al. disclose that the composition can be used to prepare a bone-like substitute that can be used for a bone such as a spine bone.

Regarding pending claims 26 and 29, the method steps would be normally performed depending on the kinetics or duration of the conversion of the precursors to poorly crystalline hydroxyapatite. Although claim 16 of '341 does not disclose a duration between 2 weeks and about 6 weeks, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the precursor materials so that the duration of the conversion process is between 2 weeks and 6 weeks, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments under "REMARKS," in Paper No. 9, filed on November 5, 2003, have been fully considered.

With respect to rejections of claims 1-13 and 16-36 under 35 U.S.C. 103(a) in view of Lee et al. ('456 patent), Applicants' arguments are not persuasive for the following reasons.

With respect to claims 1, 10, 12-13, 16, 21, 23-25, 28 and 31-32, regarding Applicants' arguments that Lee et al. do not disclose a compressive strength of at least about 60 MPa or greater, it is noted that the rationale to modify prior art does not have to be expressly stated in the prior art; the rationale to modify may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or **legal precedent established by prior case law**. *In re Fine*,

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837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Applicant's arguments do not overcome the rejections applied to the claims, since Applicants have not provided any convincing showing that the compressive strengths are nothing more than optimum or workable values as asserted by the examiner. Applicant has not provided any showing that such limitations are "critical". In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973).

Mere arguments by counsel cannot take the place of evidence. In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

A bone implant must have the compressive strength of the bone in which it is being placed so that it can function properly for the intended purpose. Thus, a bone implant should have a compressive strength greater than or equal to that of the bone in which it is being placed. Applicants' attention is directed to Agrawal et al. (US 6,187,329) disclosing typical compressive strengths of bone to be in a range of 40 to 280 MPa (col. 1, lines 44-52).

The declaration of Dr. Aliassghar N. Tofigi (Applicant), filed on November 3, 2003 under the provisions of 37 CFR §1.132 is not sufficient to overcome the rejections of claims 1-13 and 16-36 under 35 U.S.C. 103(a). An affidavit or declaration under 37 CFR §1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In the instant case, the affidavit is directed to limitations not present in the claims, such as particle size and high energy milling to produce nanometer-sized particles.

Regarding particle size of hydroxyapatite, Applicants' attention is directed to Ying et al. (US 6,013,591). Ying et al. disclose nanocrystalline hydroxyapatite that demonstrates improved strength compared to conventional polycrystalline hydroxyapatite (col. 5, lines 37-67, col. 6, lines 1-2, col. 10, lines 51-67 and col. 11, line 1).

With respect to claims 3-4, 16, 28 and 32, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26USPQ2d 1057 (Fed. Cir. 1993). Thus, "intimate mixture" as recited in the claims is inherent to thorough or complete mixing of two precursors or reactants to form a chemical compound, hydroxyapatite in the instant invention.

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With respect to claims 26 and 29, the conversion of precursors to hydroxyapatite is a time-dependent process wherein the time depends on the choice of precursors. It is well known that the time for hydroxyapatite to attain a certain "compressive strength" or to harden is a function of the precursors used. Applicants' attention is directed to Constanz et al. (US 5,336,264, col. 7, lines 55-63, col. 8, lines 62-68 and col. 9, lines 1-2). Thus, it would have been obvious to one of ordinary skill in the art to have selected precursors, as disclosed by Lee et al., so that the hardening time or time to achieve a certain compressive strength is between two to six weeks. Further, Applicants have not provided any showing that the limitation is "critical". In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973). **Mere arguments by counsel cannot take the place of evidence.** In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

The Double Patenting Rejection in the Office Action (Paper No. 9) mailed on May 2, 2003, has been withdrawn due to an error, as correctly indicated by the Applicants.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anu Ramana*
December 30, 2003

Pedro Philogene
PEDRO PHILOGENE
PRIMARY EXAMINER